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Certifier M. Bell

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 96F–0176]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of Nylon 6/12 copolymer resins as nonfood-contact layers of laminated films and rigid multilaminate constructions with polypropylene outer layers intended for use in contact with food. This action is in response to a petition filed by Toray Industries (America), Inc.

DATES: The regulation is effective (*insert date of publication in the* **Federal Register**); written objections and requests for a hearing by (*insert date 30 days after date of publication in the* **Federal Register**).

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vivian M. Gilliam, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3167.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 27, 1996 (61 FR 44067), FDA announced that a food additive petition (FAP 6B4505) had been filed by Toray Industries (America), Inc., c/o Keller and Heckman, 1001 G St. NW., suite 500 West,

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Washington, DC 20001. The petition proposed to amend the food additive regulations in Part 177 Indirect Food Additives: Polymers (21 CFR part 177) to provide for the safe use of Nylon 6/ 12 copolymers for use as a nonfood-contact layer of laminated articles intended for use with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive as a nonfood-contact layer of laminated films and rigid multilaminate constructions where the outer layers are made of polypropylene is safe, (2) the additive will achieve its intended technical effect, and (3) the regulations in §§ 177.1390 and 177.1500 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before (*insert date 30 days after date of publication in the* **Federal Register**), file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the

regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 177.1390 is amended by redesignating paragraph (c)(1)(i)(*f*) as paragraph (c)(1)(i)(*g*) and by adding a new paragraph (c)(1)(i)(*f*) to read as follows:

§ 177.1390 Laminate structures for use at temperatures of 250 °F and above.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(*f*) Nylon 6/12 resins (CAS Reg. No. 25191–04–2) complying with item 13.3 of the table in § 177.1500(b), for use as nonfood-contact layers of laminated films and in rigid multilaminate constructions with polypropylene outer layers. Laminate structures with authorized food-contact materials yield no more than 0.15 milligrams of *epsilon*-caprolactam and 0.04 milligrams of *omega*-laurolactam per square inch when extracted with 95 percent ethanol at 121 °C (250 °F) for 2 hours.

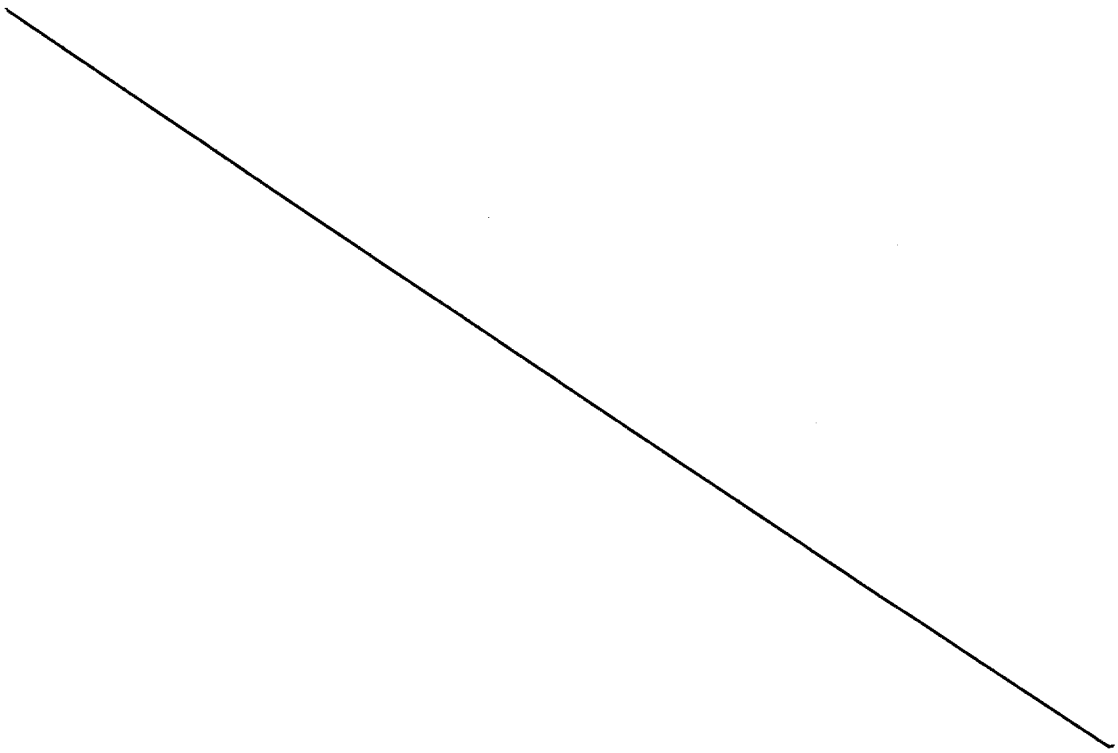
* * * * *

3. Section 177.1500 is amended in the table in paragraph (b) by adding item ''13.3'' in numerical order to read as follows:

§ 177.1500 Nylon resins.

* * * * *

(b) * * *



Nylon resins	Specific gravity	Melting point (degrees Fahrenheit)	Solubility in boiling 4.2*N* HCl	Viscosity No. (mL/g)	Maximum extractable fraction in selected solvents (expressed in percent by weight of resin)			
					Water	95 percent ethyl alcohol	Ethyl acetate	Benzene
*	*	*	*		*	*		*
13.3 Nylon 6/12 resins with residual *epsilon*-caprolactam not to exceed 0.8 percent by weight and residual *omega*-laurolactam not to exceed 0.1 percent by weight. For use only as specified in § 177.1390 of this chapter.	1.13± 0.15	400–420	Dissolves in 1 h.		1.0	1.5	0.5	0.5
*	*	*	*		*	*		*

* * * * *

Dated: 8/9/99

August 9, 1999

L. Robert Lake

L. Robert Lake
Director
Office of Policy, Planning
and Strategic Initiatives
Center for Food Safety and Applied Nutrition

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

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Michael W. Bell